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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,717	01/13/2004	Edward L. Sinofsky	104905-0008	2652

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NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,717	SINOFSKY, EDWARD L.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-25-05; 9-1-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is **final**.

The application is published application number: 2004/0147913.

The Applicant should check the application's continuity data on PAIR, as 09/382,615 is listed under "Parent Continuity Data". (The Applicant claims in the arguments section of the Amendment dated 11-22-05 that 09/382,615 represents a separate line of continuation.) This issue should be addressed in the next response.

Pending claims are 1-17. Claims 1, 10 and 17 are independent.

The IDS dated 11-25-05 and 9-1-04 are considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Koblish et al. (5,910,129).

Parentheticals and non-claim language refer to Koblish

1. A surgical ablation instrument (see figure 36-40 and relevant disclosure in col. 21:47 through col. 23:10) comprising: a housing (360 and 364) having a longitudinal lumen (370), the distal end of the housing being sufficiently flexible to be bent into a loop configuration (figures 36 and 39); an ablation element (372) disposable within (depicted in figure 38) the lumen of the housing to ablate tissue at a target site; and a fluid channel (376-370-374) within the housing for introducing fluid (from 378) to the ablation element during delivery of the ablation energy.

2. The instrument of claim 1, wherein the fluid (from 378) is delivered (374) between the ablation element (372) and the housing (364). See figures 37-38.

3. The instrument of claim 1, wherein the housing further includes a handle (18) portion at a proximal end.

4. The instrument of claim 3, wherein the handle portion includes a fluid inflow port (376, figure 38) and a fluid carrying lumen (370) for delivering the fluid to the housing (360 and 364).

5. The instrument of claim 1, wherein the distal end of the housing includes a fluid outflow port (374) for release of the fluid. Also note that 364 is porous.

6. The instrument of claim 1, wherein the fluid comprises a material (saline, col. 22:10), which cools the ablation element during delivery of ablative energy.

7. The instrument of claim 1, wherein the fluid is a lubricating fluid (saline, col. 22:10).

8. The instrument of claim 1, wherein the fluid comprises a physiologically compatible fluid (saline, col. 22:10).

9. The instrument of claim 8, wherein the fluid is saline (saline, col. 22:10).

10. A method for ablating a target tissue, comprising the steps of: providing a surgical ablation instrument comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing being sufficiently flexible to be bent into a loop configuration, an ablation element disposed within the lumen of the housing to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging

surrounding tissue. **All anticipated structure addressed prior. The anticipated structure yields the above method of use.**

11. The method of claim 10, further comprising the step of introducing a fluid between the ablation element and the housing during the energy delivery. See col. 21:65 through col. 22:5.

12. The method of claim 11, wherein the fluid comprises a material which cools the ablation element, and the step of introducing a fluid cools the ablation element during delivery of the ablative energy. See col. 21:65 through col. 22:15. The disclosure teaches the use of saline during the method of use to establish an electrically conductive path. The saline will inherently provide a cooling effect to the activated electrode.

13. The method of claim 11, wherein the fluid comprises a lubricating fluid, and the step of introducing a fluid lubricates the ablation element during delivery of the ablative energy. See col. 21:65 through col. 22:15. The disclosure teaches the use of saline during the method of use to establish an electrically conductive path. The saline will inherently provide a lubricating effect to the activated electrode.

14. The method of claim 11, further comprising the step of irrigating the target site by releasing the fluid from the housing into the target site. See col. 22:54-55, "low...liquid

perfusion is preferred." This refers to irrigation of the target site, although minimal, from the housing (364).

15. The method of claim 10, further comprising the step of repeating the steps of positioning and delivering until a composite lesion of a desired shape is formed. The Office contends it inherent that the Koblish device would require, due to its looped structure, repeating steps of positioning and delivering to create the circumferential lesions in figure 34d. Need be, the Hall patent (6,652,517, figure 15, col. 2:51-55, *inter alia*) will be introduced to prosecution disclosing the literal language of repeated advancing and rotating of the ablation element to create a circumferential lesion.)

16. The method of claim 10, wherein the target site is cardiac tissue (see figure 34d).

17. A method for ablating a target tissue, comprising the steps of: providing a surgical **epicardial (col. 20:64-67)** ablation instrument comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing being sufficiently flexible to be bent into a loop configuration an ablation element disposed within the lumen of the housing to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging

surrounding tissue. **All anticipated structure addressed prior. The anticipated structure yields the above method of use.**

Claims 1, 3, 6-10 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Stewart et al. (6,325,797).

Parentheticals refer to Stewart

1. A surgical ablation instrument (see figure 1a) comprising: a housing (22) having a longitudinal lumen ("central lumen", col. 5:33-34), the distal end of the housing being sufficiently flexible to be bent into a loop configuration (figure 1, col. 6:48-55); an ablation element (26) disposable (col. 5:29-31) within (includes the inherent inner wiring of the electrodes) the lumen of the housing to ablate tissue at a target site; and a fluid channel (col. 7:1-3) within the housing for introducing fluid to the ablation element during delivery of the ablation energy.

3. The instrument of claim 1, wherein the housing further includes a handle (24) portion at a proximal end.

6. The instrument of claim 1, wherein the fluid comprises a material (saline, col. 7:1-3) which cools the ablation element during delivery of ablative energy.

7. The instrument of claim 1, wherein the fluid is a lubricating fluid (saline, col. 7:1-3).

8. The instrument of claim 1, wherein the fluid comprises a physiologically compatible fluid (saline, col. 7:1-3).

9. The instrument of claim 8, wherein the fluid is saline (col. 7:1-3).

10. A method for ablating a target tissue, comprising the steps of: providing a surgical ablation instrument comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing being sufficiently flexible to be bent into a loop configuration (col. 6:48-55), an ablation element disposed within the lumen of the housing to ablate tissue at a target site, and a fluid channel within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging surrounding tissue (patented invention for electrical isolation, requiring lesion boundaries – protecting adjacent tissue). See patented claim 1.

15. The method of claim 10, further comprising the step of repeating the steps of positioning and delivering until a composite lesion of a desired shape is formed. Viewing figures 2c and 2d we see circumferential lesions darkly shaded around the pulmonary

vein (PV). Due to the looped design (as opposed to a design in which the ablation element in cross section is a complete circle) of the patented ablative device, repeating the positioning and delivery steps would be inherent. Otherwise, the "circumferential lesion" in figures 2c and 2d would not be entirely circumferential. (The lesion would be less than 360 degrees/discontinuous.)

16. The method of claim 10, wherein the target site is cardiac tissue (col. 1:5-8).

17. A method for ablating a target tissue, comprising the steps of: providing a surgical **epicardial (ostium, col. 4:20-29)** ablation instrument (figure 1a) comprising a housing having a proximal end, a distal end and a longitudinal lumen extending therebetween, the distal end of the housing (22) being sufficiently flexible to be bent into a loop configuration (see fig. 2a), an ablation element (26) disposed within the lumen (includes the inherent inner wiring of the electrodes 26) of the housing to ablate tissue at a target site, and a fluid channel (see col. 7:1-3) within the housing for introducing fluid to the ablation element during delivery of the ablation energy; positioning the surgical ablation instrument proximate to a predetermined tissue site; delivering ablative energy to said distal end of said housing through said ablation element, such that said target tissue is ablated without damaging surrounding tissue (patented invention for electrical isolation, requiring lesion boundaries – protecting adjacent tissue). See patented claim 1.

Response to Arguments

Applicant's arguments filed 11-22-05 have been fully considered. All prior rejections are obviated. Schaer 6,522,930 neglects to disclose a looped structure as now disclosed in each of the application's independent claims (1, 10 and 17). The Office in response presents new art above.

Double Patenting

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed **terminal disclaimer** in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **copending Application No. 10,756,645**. Although the conflicting claims are not identical, they are

not patentably distinct from each other because both groups of claims disclose a looped ablation catheter depicted in the same accompanying figures.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **copending Application No. 10,756,660**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose an ablation catheter depicted in the same accompanying figures.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **U.S. Patent No. 6,676,656**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose a looped ablation catheter depicted in the same accompanying figures.

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **U.S. Patent No. 6,558,375**. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both groups of claims disclose a looped ablation catheter depicted in the same accompanying figures.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
January 20, 2006

BEVERLY M. FLANAGAN
PRIMARY EXAMINER